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10/019,436	12/31/2001	Akira Yazaki	217151US0PCT	4227

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EXAMINER
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MORRIS, PATRICIA L

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 08/08/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/019,436

Applicant(s)

Yazaki et al

Examiner

P. Morris

Group Art Unit

1625

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- ☒ Responsive to communication(s) filed on 10/16/02
- ☒ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- ☒ Claim(s) 1-5 and 7-12 is/are pending in the application.
- ☐ Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 1-5 and 7-12 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

## Applicant Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
  - ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
  - ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
  - ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

## Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 10
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other \_\_\_\_\_

Office Action Summary

### **DETAILED ACTION**

Claims 1-5 and 7-12 are under consideration in this application.

#### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 3 and 5 are rejected under 35 U.S.C. 101 and 35 U.S.C. 112 because the claimed invention is directed to non-statutory subject matter. Claim 7 violates 35 U.S.C. 101 and 35 U.S.C. 112, since it is drafted in terms of use. See Clinical Products vs. Brenner, 255 F. Supp. 151; 149 USPQ 475 (D.C. District of Columbia 1966).

Applicants merely assert that the claims are statutory. The claims are clearly improper.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

Art Unit: 1625

evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5 and 7-12 are rejected under 35 U.S.C. 103(a) as being obvious over the combined teachings of Yazaki et al. I, II for the reasons set forth in Paper no. 5..

Again, Yazaki et al. I, II generically embrace the instant compounds having the same use. Note for example the compounds of formula (I) wherein R<sup>1</sup> represents hydrogen, R<sup>5</sup> represents an alkyl substituted azetidin-1-yl group, Y is nitrogen and R<sup>3</sup>, R<sup>4</sup>, R<sup>7</sup>, R<sup>8</sup> represent halogen.

It is believed that one having ordinary skill in the art would have found the claimed compounds *prima facie* obvious, since they are generically embraced by the disclosed formula; In re Susi, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). See also In re Malagari, 499 F.2 1297, 182 USPQ 549 (CCPA 1974); In re Lemin, 332 F.2d 839, 141 USPQ 814 (CCPA 1964); In re Rosicky, 276 F.2d 656, 125 USPQ 341 (CCPA 1960). The requisite motivation for arriving at the claimed compounds stems from the fact that they fall within the generic class of compounds disclosed by Yazaki et al. I, II. Accordingly, one having ordinary skill in the art would have been motivated to prepare any of the compounds embraced by the disclosed generic formula, including those encompassed by the claims, with the expectation that each of them would be suitable as antibacterial agents.

Applicants appear to argue that one having ordinary skill in the art would not have been motivated to produce the compounds encompassed by the claims. The motivation is not abstract but is always related to the properties or uses that one having ordinary skill in the art would have

Art Unit: 1625

expected the resulting compound to exhibit. In situations involving chemical compounds bearing a close structural similarity, the requisite motivation stems from the expectation that compounds exhibiting closely similar structures will exhibit similar properties. In the situation here, one would not have to modify the disclosure of Yazaki et al. I, II, but merely employ compounds that are generically embraced by the disclosed formula of Yazaki et al. I, II. As previously discussed, the requisite motivation for producing the claimed compounds stems from the fact that they are generically disclosed by Yazaki et al. I, II. Therefore, one having ordinary skill in the art would have found it *prima facie* obvious to select any on the compounds embraced by the generic formula, including those of the claims, with the expectation that each of them can be used as an antimicrobial agent. The close structural analogy to the prior art provides the motivation to make and use the instant compounds as antibacterial agents; In re Wood, 199 USPQ 137; In re Payne, 203 USPQ 245 (both CCPA).

Further, Yazaki et al. I, II teach a compound differs from the compound claimed herein as a alkyl homolog. Note example 75 and claim 9 of Yazaki et al. I. One having ordinary skill in the art would have been motivated by the disclosure of the prior art compound to arrive at the claimed compound. The motivation to make the instant compound is its close structural similarities to the disclosed compound. Note that the disclosed compound has antimicrobial activity, thus the skilled artisan would expect such structurally similar compounds to possess similar properties.

Contra to applicants' arguments in the instant response, a compound need not be a homolog or isomer of a prior art compound in order to be susceptible to a rejection based on structural obviousness. The name used to designate the structural relationship between compounds is not

Art Unit: 1625

controlling, it is the closeness of that relationship. Note: In re Payne et al., 203 USPQ 245.

When chemical compounds have a “very close” structural similarity and similar utilities, a prima facie case of obviousness may be made, note In re Grabiak, 226 USPQ 870, “without more”.

Thus, a difluorinated compound was held unpatentable over the prior art dichloro compound on the basis of similar reasoning to the above; Ex parte Wiseman (POBA 1953) 98 USPQ 277.

Obviousness can be based on the concept of “isoterism”, the substitution, in the parent compound, of one atom or group of atoms for another atom or group of atoms having similar properties, such as electronic or steric configuration; Ex parte Engelhardt, (POBA 1980) 208 USPQ 243.

Applicants assert in the instant response that they have shown unobvious properties. The data in the specification, while interesting, is of little, if any, probative value since it is not commensurate in scope with the claims. Table 1 on page 22 shows that the instant compound has the same activity towards many of the same bacteria. Applicants’ claims are drawn to the treatment of all microbes including fungi and yet the data in the specification treats only bacteria. Table 2 on page 23 shows that the closest prior art compound (comp. com’d 1) and the instant compound show the same results. Little can be said about the activity towards the many untested bacteria, fungi, parasites, etc. Applicants’ burden is to submit sufficient evidence “to permit a conclusion respecting the relative effectiveness of applicants’ claimed compounds and the compounds of the prior art”, In re Johnson, 223 USPQ 1260; In re Payne, supra. The evidence presented by applicants all indicate that there is little uniformity of result. In fact the prior art and claimed compounds show the same activity. No unexpected results are noted.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 7, 11 and 12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating bacterial infections, does not reasonably provide enablement for the treatment of any and all microbes. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

No enablement is shown for the treatment of microbial infections. The tests set forth in the specification are insufficient for treating any and all microbes.

The disclosure provides no indication of whether the compounds treat all microbes, such as fungi, viruses, parasites, etc.

Applicants' disclosure fails to provide a description of a method of treating all microbes in a single infected host. Methods of treating a specific condition with a active agent, whether old or new, should be enabled by a written decription containing a statistically significant example, which should include the organism treated. Applicants have not provided such a disclosure. Moreover, applicants' statements with regard to the various dosages and modes of administration of the quinoline compound, for the treatment of all infectious diseases are merely speculative, since nowhere in the specification as filed, is described a method of treating all microbial diseases, *in vivo* in a single patient.

Art Unit: 1625

Thus, applicants' situation is much like that of In re Kirk, 153 USPQ 48: "What the applicants are really saying to those skilled in the art is take the compound, experiment, and find out what it treats".

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Again, Claims 1-5 are substantial duplicates. Claims 1 and 2 are substantial. Is claim 2 intended to be a composition claim? It appears that applicants think a medicine is a composition, which is not the case. The term medicine fails to clearly define the claim as a **composition**. If so, then claim is a substantial duplicate of claim 4. If claims 2, 3 and 5 are intended to be composition claims, then they are not proper because they fail to recite an inert carrier. The term "medicine" does not distinguish the claims from the compound claims. As discussed supra, claims 3 and 5 are not even drawn statutory subject matter.



### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-5 and 7-12 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 5,998,436. Although the conflicting claims are not identical, they are not patentably distinct from each other because for the reasons set forth in Paper no. 5.

A terminal disclaimer has not been received too date..

Claims 1-5 and 7-12 are directed to an invention not patentably distinct from claims 1-11 of commonly assigned US 5,998,436. Specifically, the instant compound is generically embraced therein.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302). Commonly assigned US 5,998,436, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee is required under 37 CFR 1.78(c) and 35 U.S.C. 132 to either show that the conflicting inventions were commonly owned at the time the invention in this application was made or to name the prior inventor of the conflicting subject matter. Failure to comply with this requirement will result in a holding of abandonment of the application.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

### ***Conclusion***

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

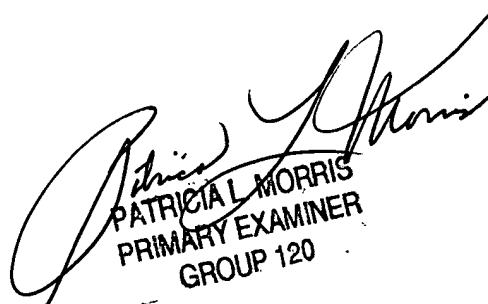
Art Unit: 1625

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ms. Morris whose telephone number is (703) 308-4533.

plm

August 7, 2003



PATRICIA L. MORRIS  
PRIMARY EXAMINER  
GROUP 120